Logansport Memorial Hospital

April 25, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Department of Health and Human Services
Food and Drug Administration
21 CFR Parts 16 and 900
[Docket No. 99N-4578]
State Certification of Mammography Facilities
Proposed Rule

To Whom It May Concern:

As management and administration at Memorial Hospital in Logansport, Indiana, we respond respectfully to the Proposed Rule of State Certification of Mammography Facilities. Our comments are postured in the preservation and continuance of standards that seek to maintain and improve quality in healthcare. The Mammography Quality Standards Act of 1992 (MQSA) was established to create and maintain a minimum national quality standard in mammography. The stringent requirements of the Food and Drug Administration (FDA) certification process ensure compliance to the standards contained in the MQSA. Our comments seek to preserve the MQSA standards. The FDA is exploring the possibility of State Certifying Agencies. The agencies would act under the auspices of the FDA in enforcing the standard contained in the MQSA. The areas of concern that have the greatest implication are program efficacy and cost.

Would State Certifying Agencies enforce the MQSA standards as stringently and efficaciously as the FDA? The primary concern is that consistency and continuity would be surrendered in ascribing this authority to state agencies or entities, thereby compromising the stringency espoused by the FDA. The concern is not who holds the certifying authority, but rather how the authority will be imposed. Moreover, it is feared that multiple agencies/entities will not be able to render consistent authority consistent with the intent of the FDA and the MQSA. Indeed the quality of mammography could deteriorate over time if this type of certifying relationship were allowed to continue without strict oversight by the FDA. This would require the FDA to impose extensive and active review of the State Certification Authorities.

Section 900.23 proposes standards for the annual evaluations of the State Certification Authorities. However, the extent of that annual evaluation is not clear. Would the FDA conduct follow-up inspections that would serve to validate State Certifying inspections? How frequent and intensive would these follow-up inspections be? How would discrepancies between the inspections be handled and what would the implication be for the inspected facility? Could the FDA implement an evaluative program without incurring unreasonable cost?

The impact analysis contained within the Proposed Rule indicates that a given number of states with particular characteristics must agree to enter the State Authority Certification (SAC) program. Is it expected that the FDA would only proceed if a cost savings could be effectuated? The cost passed on to the public may be beneficial if the FDA approved mammography sites had distinct advantage and endorsement from the FDA. This would serve to enhance and improve quality.

Memorial Hospital supports any Federal policy that seeks the preservation and enhancement of quality in mammography. If the FDA can effectively accomplish the State Certification Authority Program without incurring an undue financial, compliance or legal burden on the mammography facilities or public, then this Proposed Rule should be pursued.

Sincerely,

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ADDRESS CORRECTION REQUESTED

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